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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,649	06/04/2002	Pierre Belhumeur	1051-1-019	6750
7590 Klauber & Jackson 411 Hackensack Avenue Hackensack, NJ 07601		05/01/2007	EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,649	<b>Applicant(s)</b> BELHUMEUR ET AL.	
	<b>Examiner</b> Taeyoon Kim	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-13 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### DETAILED ACTION

Claims 3-13 are pending.

#### ***Response to Amendment/Arguments***

Applicant's amendment and response filed on Dec. 4, 2006 has been received and entered into the case.

Claims 1 and 2 are canceled, claims 3-13 are pending and have been considered on the merits. All arguments have been fully considered.

Claim rejections in the previous office action have been withdrawn due to the amendment. Therefore, the applicant's arguments are moot.

However, the examiner would like to point out that in the claim rejection under 35 U.S.C. §112, 1<sup>st</sup> paragraph to claim 2 (now cancelled) where the examiner discussed unpredictability how to identify unknown prion degradation indicator, A $\beta$  protein was used as an example not as a prion protein, but as a protein sharing structural limitations of detergent insolubility and amyloid formation with known prion proteins. Because of lack of guidance how to identify new unknown prion proteins except known physicochemical features shared by known prion proteins (detergent insolubility and formation of amyloid filament), it is not clear how a person of ordinary skill in the art would identify such proteins, and there is no clear support in the specification that a person of ordinary skill in the art at the time of the invention made to possess such unknown new prion proteins from *Saccharomyces cerevisiae* or *Podospora anserina* except known prion or prion-like proteins (see below).

***Notice to Comply with Requirements for Patent Applications Containing  
Nucleotide Sequence and/or Amino Acid Sequence Disclosures***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. **All sequences disclosed in the application must comply with the requirements of 37 C.F.R. 1.821-1.825, not only those recited in the claims.**

There are two sequences listed in the specification: p.8 lines 29 and 31.

All such sequences are relevant for the purposes of building a comprehensive database and properly assessing prior art. It is therefore essential that all sequences, whether only disclosed or also claimed, be included in the database.

***Claim Objections***

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation disclosed in claim 6 of "a fungus" is broader than the limitation given in the parent claim. Claim 3 (independent claim) has a limitation of *Saccharomyces cerevisiae* or *Podospora anserina*, however, claim 6, dependent on claim 3, has a limitation of a fungus (2<sup>nd</sup> line).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1651

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "the steps" in 2<sup>nd</sup> line. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 6-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The current claims are drawn to indicators obtainable from *Saccharomyces cerevisiae* or *Podospora anserina*. As disclosed in claim 5, Sup35p, Ure2p, Het-s proteins are examples of such indicators because they are prion proteins from these fungi. However, the specification does not contain an adequate description of unknown and/or unidentified indicators, an analog, recombinant for, a mutant or a fragment of these indicators obtainable from these fungi.

The claims are not limited to a particular species just generically any indicator, which is known in the art and those which have not been isolated and/or identified including variants (an analog, recombinant for, a mutant or a fragment) of known

Art Unit: 1651

indicators which might not necessarily be prion proteins. For example, unknown proteins translated from genes of *Saccharomyces cerevisiae* or *Podospora anserina* with similar characteristics as prion proteins under a sterilization process would be qualified as such indicators. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

It is implied that so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim, one can thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. This argument is not entirely without merit. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166

Breadth alone is not the issue, however. In *re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that: "Inventor should be allowed to dominate future patentable

inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

The claims imply that other indicators with the claim-designated properties can be found using the method disclosed in the specification without undue experimentation. Whether or not the disclosure provides an enabling disclosure, it does not provide a written description of the desired cell population which is necessary to provide a written description of the claimed cell population. Every species in a genus need not be described in order that a genus meets the written description requirement. See *Utter*, 845 F.2d at 998- 99,6 USPQ2d at 1714 ("A specification may, within the meaning of §112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") In claims to an species from a

Art Unit: 1651

genus, however, a generic statement without more, is not an adequate written description of the genus because it does not distinguish the claimed species of the genus from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally thought to exist, in the absence of knowledge as to what that material consists of, is not a description of that entire material.

#### ***Allowable Subject Matter***

Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.



**Conclusion**


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651



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